

We Claim:

1. An abuse-resistant controlled-release pharmaceutical composition, comprising discrete particles of a pharmaceutically effective amount of an active compound capable of abuse, wherein said discrete particles comprise surfaces that are wetted with a coating material that is insoluble in water.
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2. An abuse-resistant composition according to claim 1, wherein said particles are distributed throughout a matrix comprising said coating material.
3. An abuse-resistant composition according to claim 2 wherein said particles are water-soluble.
- 10 4. An abuse-resistant composition according to claim 3 wherein said matrix material is non-erodable at pH less than about 6.
5. An abuse-resistant composition according to claim 4 wherein said matrix material is erodable in the presence of bile salts and lipase.
- 15 6. An abuse-resistant composition according to claim 2 wherein said particles are distributed throughout said matrix.
7. An abuse-resistant composition according to claim 1 wherein said compound is a narcotic.
8. An abuse-resistant composition according to claim 3 wherein the application of mechanical stress to said matrix increases the aqueous dissolution of active in said composition by less than about 15% of said pharmaceutically effective amount in the first hour, and does not substantially modify the dissolution rate of said composition thereafter.
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9. An abuse-resistant composition according to claim 8 wherein the application of mechanical stress to said matrix increases the aqueous dissolution of active in said composition by less than about 10% of said pharmaceutically effective amount in the
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first hour, and does not substantially modify the dissolution rate of said composition thereafter.

10. An abuse-resistant composition according to claim 8 wherein said mechanical stress comprises crushing said composition.

5 11. An abuse-resistant controlled-release pharmaceutical composition according to claim 1 for administration to a subject in need thereof from once to four times a day.

12. A method for the preparation of an sustained release pharmaceutical composition having a reduced potential for abuse, comprising:

10 (a) providing a pharmaceutically active compound capable of inducing in a subject a reaction that is physiologically or psychologically addictive if administered in an immediate release dosage form;

(b) applying a pressure force to a mixture comprising particles of said compound and a water insoluble material thereby resulting in surface coated particles; and

15 (c) incorporating said surface coated particles into a pharmaceutical composition that when subjected to stress does not increase substantially the immediate release of said compound in an aqueous environment.

13. A method according to claim 12 wherein said force is applied to a dispersion of said particles in a flowable medium comprising said material.

20 14. A method according to claim 13 wherein said force is an abrupt pressure force.

15. A method according to claim 13 wherein said force is an ultrasonic force.

16. A method according to claim 13 wherein said force is piston generated shock wave.

17. A method according to claim 13 wherein said particles are micronized.

25 18. A method according to claim 17 wherein said particles have a mean particle size of less than about ten microns.

19. A method according to claim 13 wherein said material comprises a polymorphic wax
20. A method according to claim 19 wherein said wax comprises a hydrogenated vegetable wax, a tri-, di- or mono-glyceride, or a mixture thereof.
21. A method according to claim 20 wherein said material comprises a polymeric material
5 that is water insoluble, and erodable in the intestinal tract at pH greater than about 6.
22. A method according to claim 13 further comprising solidifying said dispersion into microspheres.
23. A method according to claim 12 wherein the application of mechanical stress to said
10 composition modifies the aqueous dissolution of said compound by an increase of less than about 15% of said pharmaceutically effective amount in the first hour, and does not substantially modify the dissolution rate of said composition thereafter.
24. A dosage form according to claim 7 wherein said narcotic is selected from the group
15 consisting of fentanyl, sufentanil, carfentanil, lofentanil, alfentanil, hydromorphone, oxycodone, hydroxycodone, propoxyphene, pentazocine, methadone, tilidine, butorphanol, buprenorphine, levorphanol, codeine, oxymorphone, meperidine, dihydrocodeinone and cocaine.